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CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Receipt No: 7002 0860 0000 6598 0836

September 29, 2005

John Paul, ESHA Manager
Clariant Corporation
500 Washington Street
Coventry, Rhode Island 02816

Re: Application for Re-Processing of PCB-Contaminated Pigments

Dear Mr. Paul:

This is in response to the Clariant Corporation (Clariant) *Application to Rework PCB-Contaminated Pigment Product*, dated June 27, 2005 and received by EPA on July 7, 2005 (Application). This Application was submitted by Clariant to support its process for the re-processing of contaminated pigments containing PCBs greater than 50 parts per million (> 50 ppm) which were inadvertently generated during manufacturing.

EPA has reviewed the Application and provides the following comments.

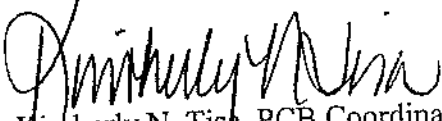
1. The title page contains the designation "Attorney-Client Privilege Confidential Business Information"; Section 1 inventory page contains the designation "TSCA Confidential Information". It is unclear if Clariant is claiming this Application as TSCA Confidential Business Information (CBI) or is claiming just CBI. For any submittal that is claimed TSCA CBI, you must clearly identify the portions that are claimed TSCA CBI, include two sanitized versions and address the submittal to the Document Control Officer (Rosina Toscano, mailcode SEP) directly. Please be aware that a claim of TSCA CBI for certain portions of the Application may be problematic, especially for evaluation of analytical methodology. Accordingly, Clariant may wish to consider claiming certain portions (such as inventory) TSCA CBI, and the remainder as CBI under 40 CFR Section 2.203b. If you wish to claim some or all of the information you submit as CBI, you must follow the procedures described in EPA's regulations at 40 C.F.R. Part 2, Subpart B.
2. Clariant has provided insufficient information for EPA's evaluation of the process design. Section 5 contains a simplified process flow chart procedure for reworking the contaminated pigments. However, EPA finds the procedure difficult to follow and is unable in many cases to find the steps referenced in the procedure. It would be helpful if Clariant could provide a schematic of the system design.

3. Flow Diagram, Section 5. There are 2 pathways for solvent recovery; one pathway indicates PCB contaminated solvent and the other pathway shows clean solvent.
 - a. For the 1st pathway, it appears that this is the pathway for the distilled PCBs from the slurry solution. It is unclear what the distillation temperature is and if it is satisfactory for the PCB congeners of interest.
 - b. The second pathway indicates clean solvent, which may be a misnomer. In the procedure, there appears to be a PCB maximum limit for the clean solvent of 3 ppm. If so, the solvent is not technically "clean" as is inferred in the diagram.
4. The analytical method (Section 6) for the proposed project is Clariant Method GC001.
 - a. EPA cannot fully evaluate this method as the GC001-Addendum 1 for standard preparation was not included in the Application.
 - b. Step 5.4.1.2, last paragraph. The step refers to addition of anhydrous sodium sulfate for removal of sulfuric acid. Please note that this explanation is slightly misleading. The sodium sulfate will remove **water** from the solution. Since the water contains the sulfuric acid, it will be removed with the water.
 - c. The method proposes GC calibration using 3 tetrachlorobiphenyl (TCB) standards: The only data presented in the Application reported the PCBs as "total PCBs" and did not include the specific congeners identified. As such, EPA can make no determination on the adequacy of the selected calibration standards.
 - d. The method contained no information on calibration procedures or on data quality and method evaluation.
5. Page 3 of the narrative (schedule discussion) refers to reworking of pigment material containing < 50 ppm and that all results have been successful. Clariant should include any information pertaining to this reworking in this Application. For example, a discussion of the materials reworked, the procedure employed, and the pre- and post-reworking PCB analytical results should be included.

As a point of clarification, please be aware that a Consent Agreement and Final Order (CAFO) will need to be executed to return PCB-contaminated product from Mexico for purposes of "reworking". In addition, since the PCB-contaminated product currently stored at Clariant is unauthorized, the CAFO must be executed and include a reference to the Application or any workplan approved by EPA prior to "reworking" of this product.

Should you have any questions, please feel free to call me at (617) 918-1527.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kimberly N. Tisa', written in a cursive style.

Kimberly N. Tisa, PCB Coordinator
Office of Ecosystem Protection/Chemical Management Branch

cc: M. Milette, EPA
T. Olivier, EPA

(e) *High efficiency boiler facilities.* Each owner or operator of a high efficiency boiler used for the disposal of liquids between 50 and 500 ppm PCB shall collect and maintain for a period of 5 years the following information, in addition to the information required in paragraph (b) of this section:

(1) For each month PCBs are burned in the boiler the carbon monoxide and excess oxygen data required in § 761.71(a)(1)(viii) and § 761.71(b)(1)(viii);

(2) The quantity of PCBs burned each month as required in § 761.71(a)(1)(vii) and § 761.71(b)(1)(vii); and

(3) For each month PCBs (other than mineral oil dielectric fluid) are burned, chemical analysis data of the waste as required in § 761.71(b)(2)(vi).

(f) *Retention of special records by storage and disposal facilities.* In addition to the information required to be maintained under paragraphs (b), (c), (d) and (e) of this section, each owner or operator of a PCB storage or disposal facility (including high efficiency boiler operations) shall collect and maintain for the time period specified in paragraph (b) of this section the following data:

(1) All documents, correspondence, and data that have been provided to the owner or operator of the facility by any State or local government agency and that pertain to the storage or disposal of PCBs and PCB items at the facility.

(2) All documents, correspondence, and data that have been provided by the owner or operator of the facility to any State or local government agency and that pertain to the storage or disposal of PCBs and PCB items at the facility.

(3) Any applications and related correspondence sent by the owner or operator of the facility to any local, State, or Federal authorities in regard to waste water discharge permits, solid waste permits, building permits, or other permits or authorizations such as those required by §§ 761.70(d) and 761.75(c).

(g) *Reclassification records.* If you reclassify electrical equipment using the procedures in § 761.30(a)(2)(v) or § 761.30(h)(2)(v), you must keep records showing that you followed the required reclassification procedures. Where these procedures require testing, the

records must include copies of pre- and post-reclassification PCB concentration measurements from a laboratory using quality control and quality assurance procedures. You must make these records available promptly to EPA or to any party possessing the equipment through sale, loan, lease, or for servicing. You must retain the records for at least 3 years after you sell or dispose of the equipment.

(Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and further redesignated at 47 FR 37360, Aug. 25, 1982; 49 FR 28191, July 10, 1984; 53 FR 12524, Apr. 15, 1988; 54 FR 52750, Dec. 21, 1989; 55 FR 26205, June 27, 1990; 58 FR 34205, June 23, 1993; 63 FR 35461, June 29, 1998; 66 FR 17619, Apr. 2, 2001]

§ 761.185 Certification program and retention of records by importers and persons generating PCBs in excluded manufacturing processes.

(a) In addition to meeting the basic requirements of § 761.1(f) and the definition of excluded manufacturing processes at § 761.3, manufacturers with processes inadvertently generating PCBs and importers of products containing inadvertently generated PCBs must report to EPA any excluded manufacturing process or imports for which the concentration of PCBs in products leaving the manufacturing site or imported is greater than 2 micrograms per gram (2 µg/g, roughly 2 ppm) for any resolvable gas chromatographic peak. Such reports must be filed by October 1, 1984 or, if no processes or imports require reports at the time, within 90 days of having processes or imports for which such reports are required.

(b) Manufacturers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the number, the type, and the location of excluded manufacturing processes in which PCBs are generated when the PCB level in products leaving any manufacturing site is greater than 2 µg/g for any resolvable gas chromatographic peak. Importers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the concentration of PCBs in imported products when the PCB concentration

of products being imported is greater than 2 µg/g for any resolvable gas chromatographic peak. Persons must also certify the following:

(1) Their compliance with all applicable requirements of §761.1(f), including any applicable requirements for air and water releases and process waste disposal.

(2) Whether determinations of compliance are based on actual monitoring of PCB levels or on theoretical assessments.

(3) That such determinations of compliance are being maintained.

(4) If the determination of compliance is based on a theoretical assessment, the letter must also notify EPA of the estimated PCB concentration levels generated and released.

(c) Any person who reports pursuant to paragraph (a) of this section:

(1) Must have performed either a theoretical analysis or actual monitoring of PCB concentrations.

(2) Must maintain for a period of three years after ceasing process operations or importation, or for seven years, whichever is shorter, records containing the following information:

(i) *Theoretical analysis.* Manufacturers records must include: the reaction or reactions believed to be generating PCBs; the levels of PCBs generated; and the levels of PCBs released. Importers records must include: the reaction or reactions believed to be generating PCBs and the levels of PCBs generated; the basis for all estimations of PCB concentrations; and the name and qualifications of the person or persons performing the theoretical analysis; or

(ii) *Actual monitoring.* (A) The method of analysis.

(B) The results of the analysis, including data from the Quality Assurance Plan.

(C) Description of the sample matrix.

(D) The name of the analyst or analysts.

(E) The date and time of the analysis.

(F) Numbers for the lots from which the samples are taken.

(d) The certification required by paragraph (b) of this section must be signed by a responsible corporate officer. This certification must be main-

tained by each facility or importer for a period of three years after ceasing process operation or importation, or for seven years, whichever is shorter, and must be made available to EPA upon request. For the purpose of this section, a responsible corporate officer means:

(1) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation.

(2) The manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding \$25,000,000 (in second quarter 1980 dollars), if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(e) Any person signing a document under paragraph (d) of this section shall also make the following certification:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate information. Based on my inquiry of the person or persons directly responsible for gathering information, the information is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for falsifying information, including the possibility of fines and imprisonment for knowing violations.

Dated: _____
Signature: _____

(f) This report must be submitted to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: PCB Notification. This report must be submitted by October 1, 1984 or within 90 days of starting up processes or commencing importation of PCBs.

(g) This certification process must be repeated whenever process conditions

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are significantly modified to make the previous certification no longer valid.

(Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 28191, July 10, 1984; 49 FR 33019, Aug. 20, 1984, as amended at 53 FR 12524, Apr. 15, 1988; 58 FR 34205, June 23, 1993; 59 FR 33697, June 30, 1994; 60 FR 34465, July 3, 1995]

§ 761.187 Reporting importers and by persons generating PCBs in excluded manufacturing processes.

In addition to meeting the basic requirements of § 761.1(f) and the definition of excluded manufacturing process at § 761.3, PCB-generating manufacturing processes or importers of PCB-containing products shall be considered "excluded manufacturing processes" only when the following conditions are met:

(a) Data are reported to the EPA by the owner/operator or importer concerning the total quantity of PCBs in product from excluded manufacturing processes leaving any manufacturing site in any calendar year when such quantity exceeds 0.0025 percent of that site's rated capacity for such manufacturing processes as of October 1, 1984; or the total quantity of PCBs imported in any calendar year when such quantity exceeds 0.0025 percent of the average total quantity of such product containing PCBs imported by such importer during the years 1978, 1979, 1980, 1981 and 1982.

(b) Data are reported to the EPA by the owner/operator concerning the total quantity of inadvertently generated PCBs released to the air from excluded manufacturing processes at any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(c) Data are reported to the EPA by the owner/operator concerning the total quantity of inadvertently generated PCBs released to water from excluded manufacturing processes from any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(d) These reports must be submitted to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania

§ 761.202

Ave., NW., Washington, DC 20460, ATTN: PCB Notification.

(Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 28192, July 10, 1984, as amended at 53 FR 12524, Apr. 15, 1988; 58 FR 34205, June 23, 1993; 59 FR 33697, June 30, 1994; 60 FR 34465, July 3, 1995]

§ 761.193 Maintenance of monitoring records by persons who import, manufacture, process, distribute in commerce, or use chemicals containing inadvertently generated PCBs.

(a) Persons who import, manufacture, process, distribute in commerce, or use chemicals containing PCBs present as a result of inadvertent generation or recycling who perform any actual monitoring of PCB concentrations must maintain records of any such monitoring for a period of three years after a process ceases operation or importing ceases, or for seven years, whichever is shorter.

(b) Monitoring records maintained pursuant to paragraph (a) of this section must contain:

- (1) The method of analysis.
- (2) The results of the analysis, including data from the Quality Assurance Plan.
- (3) Description of the sample matrix.
- (4) The name of the analyst or analysts.
- (5) The date and time of the analysis.
- (6) Numbers for the lots from which the samples are taken.

(Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 28193, July 10, 1984, as amended at 58 FR 34205, June 23, 1993]

Subpart K—PCB Waste Disposal Records and Reports

SOURCE: 54 FR 52752, Dec. 21, 1989, unless otherwise noted.

§ 761.202 EPA identification numbers.

(a) *General.* Any generator, commercial storer, transporter, or disposer of PCB waste who is required to have an EPA identification number under this subpart must notify EPA of his/her PCB waste handling activities, using the notification procedures and form

**U.S. Food and Drug Administration****CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)[510 \(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
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[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR109.30]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICESPART 109--UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-
PACKAGING MATERIAL

Subpart D--Naturally Occurring Posionous or Deleterious Substances

Sec. 109.30 Tolerances for polychlorinated biphenyls (PCB`s).

(a) Polychlorinated biphenyls (PCB`s) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB`s have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB`s as unavoidable, environmental contaminants. PCB`s are transmitted to the food portion (meat, milk, and eggs) of food-producing animals ingesting PCB-contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB`s which may migrate to the packaged food. The source of PCB`s in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB`s) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB`s as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term ``polychlorinated biphenyls (PCB`s)`` is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB`s is present as the residue. The temporary tolerances for residues of PCB`s are as follows:

- (1) 1.5 parts per million in milk (fat basis).
- (2) 1.5 parts per million in manufactured dairy products (fat

basis).

- (3) 3 parts per million in poultry (fat basis).
- (4) 0.3 parts per million in eggs.
- (5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).
- (6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.
- (7) 2 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

- (8) 0.2 parts per million in infant and junior foods.
- (9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled ``Analytical Methodology for Polychlorinated Biphenyls, June 1979`` for determining compliance with the tolerances established in this section is available from the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

(c) A barrier is functional for purposes of paragraph (a)(9) of this section if the barrier limits migration of PCB's from the packaging material to food to a level not exceeding the migration which occurs under the same test conditions from packaging material containing 10 parts per million PCB without the use of a barrier. A class of barrier material is functional for purposes of paragraph (a)(9) of this section if a representative barrier of the class limits migration of PCB's from the packaging material to food to a level not exceeding the migration which occurs under the same test conditions from packaging material containing 10 parts per million PCB without the use of a barrier. Migration levels shall be determined for purpose of this paragraph solely by use of testing conditions described in ``Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983``, which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. A class of barrier material shall be deemed functional only if the definition of the class and the designation of one or more representative barriers has been approved by the Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration. In the event that the Director, Center for Food Safety and Applied Nutrition, does not approve a proposal made to the Center regarding the definition of a class of barrier material or the designation of representative barriers, the Director shall advise the person making the proposal of the reasons for the Center's disapproval within 90 days of receipt of the proposal. All proposals for definition of classes and determinations of the Food and Drug Administration regarding such proposals shall be on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

(d) Any person who asserts that a barrier or class of barriers is functional shall submit the results of tests conducted to determine the functionality of the barrier or class of barriers to Center for Food

Safety and Applied Nutrition (HFS-308), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. All barriers or classes of barriers shall be tested with the four solid food receptors specified in ``Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983``, which is incorporated by reference. The availability of this reference is given in paragraph (c) of this section. The test results as to each barrier shall be accompanied by (1) a description of the barrier's composition adequate to enable identification; and (2) a specific definition of the barrier by relevant technical characteristics. The Center for Food Safety and Applied Nutrition shall review submitted test results promptly. Within 60 days of the receipt of test results, the Director, Center for Food Safety and Applied Nutrition, shall notify the person submitting the test results whether the tests were conducted in accordance with the ``Analytical Methodology for Polychlorinated Biphenyls; June 1979``, which is incorporated by reference, or the ``Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983`` and whether, therefore, the barrier or class of barriers is deemed functional within the meaning of paragraph (c) of this section. The test results and any response of the Food and Drug Administration shall be placed on file with the Dockets Management Branch, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

[42 FR 52819, Sept. 30, 1977, as amended at 44 FR 38340, June 29, 1979; 46 FR 8459, Jan. 27, 1981; 48 FR 10811, Mar. 15, 1983; 48 FR 37021, Aug. 16, 1983; 54 FR 24892, June 12, 1989; 59 FR 14364, Mar. 28, 1994; 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

Effective Date Note: At 38 FR 22794, Aug. 24, 1973, the following appeared concerning Sec. 109.30(a)(9) (formerly 122.10(a)(9)):
* * * Sec. 109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by Sec. 109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C--Regulatory Limits for Added Poisonous or Deleterious Substances
[Reserved]

Subpart D--Naturally Occurring Poisonous or Deleterious Substances
[Reserved]

Database Updated April 1, 2003